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From: DiNatale, Margaret (DPH)
Sent: Thursday, November 08, 2007 11:26 AM
To: Han, Linda (DPH); Nassif, Julianne (DPH); Nawn, Kathleen (DPH); Smole, Sandra (DPH); Werner, Barbara (DPH); Goldbaum, Robert (DPH); Liu, Donghui (DPH); Konomi, Raimond (DPH); Chen, Karen (DPH); Wang, Xingtai (DPH); Hennigan, Scott (DPH); Krumholz, Glenn (DPH); Boyd, Rozelta (DPH); Stiles, Tracy (DPH); Belanger, Peter (DPH); Kazianis, Arthur (DPH); Westerling, Judith; Gauthier, Cheryl (DPH); Nassif, Julianne (DPH); Alfonso, Felipe (DPH); Servizio, Paul (DPH); Clemmer, Jill (DPH); Salemi, Charles (DPH); Elvin, Paul (DPH)
Cc: Caloggero, Dina (DPH); DiNatale, Margaret (DPH); Gilchrist, Mary (DPH); Nagle, Austin (DPH)
Subject: update on the flow of documents
Attachments: SOP In process review.dot

Hello,

As we move through the transition phase, there will be unforeseen glitches that we will need to address. The review and routing of various documents is a recent glitch. I will attempt to summarize these two issues in this email. These two items will also be discussed in a follow up meeting. In the meantime, if you need clarification or if the system outlined in this email isn't working please let me know and we can discuss it.

Thanks for your patience during this transition,
Peggy DiNatale

To follow this email: Please refer to the "Records Review Schedule" chart. This document was distributed at the QI Planning meeting that was held on Oct. 22 and it is available on the F drive: Common / Quality Assurance folder / QI documents / Records Review Schedule.

All records begin with the Technical Supervisor and the move on to the Lab. Div. Director.

1. Records on the chart marked with an "X" for QA only

Documents: New Employee CLIA paperwork, 6 month Competency Assessment for new employees, Checklist for introduction of a new test

These documents are to be given to the QA Office in room 454, Peggy DiNatale. When submitting these documents to QA, please either place them in a folder marked with your name and lab or use the old In Process Review Form⁽¹⁾ from QA SOP, QA.013 (a copy is attached and is now available on the F common drive in the QI document folder).

NOTES: (1) This In Process Review form may be revised over the next few months but for now, we will use the current version.

2. Records on the chart marked with an "X" for QA and Dr. Gilchrist

Documents: Annual SOP Inventory, Validation plan, Validation summary, New SOP, Major revision to SOP, Revisions to Test report, Annual review of test reports, proficiency survey results⁽²⁾ for PT surveys sent directly to the Lab, in-house proficiency panels, corrective actions

These documents are to be reviewed and signed by the Technical Supervisor and the Lab. Div. Director and then given to the QA Office in room 454, Peggy DiNatale. Peggy will route these to Dr. Gilchrist. When submitting these documents use the old In Process Review Form⁽¹⁾ from QA SOP, QA.013 (a copy is attached and is now available on the F common drive in the QI document folder).

NOTE: (1) This In Process Review form may be revised over the next few months but for now, we will use the current version.

(2) Proficiency survey results that are delivered directly to the QA office will be entered into a tracking database then

routed from QA to the Technical Supervisor. The Technical Supervisor will review, sign and then discuss with the Lab.

Div. Director, who will also sign. Then the survey results will be given back to QA. QA will take care of routing it to Dr.

Gilchrist. This is done so that QA remains in the loop and to ensure that we, as an organization, have all PT survey

results tracked and maintained in a central location.

3. Records on the chart marled with an "X" for Dr. Gilchrist

Documents: Verification of electronic result transmission, verification automated or computer generated calculations, pipette calibrations, semi annual correlation of instruments, QC on test runs, new lot verifications, equipment maintenance, send out logs,

These documents are to be reviewed and signed by the Technical Supervisor and the Lab. Div. Director and then given to Austin Nagle in the Administration Office. When submitting these documents, use the new QA Reporting Coversheet. This sheet is available on the F common drive in the QI documents folder. This sheet was sent to all Technical Supervisors and Lab Div. Directors via email on October 23.